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Kristin L. Apuzzo
(TYPED OR PRINTED NAME OF PERSON MAILING PAPER OR FEE)

Kristin L. Apuzzo
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard Leslie Edelson	Group Art Unit: 1632
on METHODS FOR INDUCING THE DIFFERENTIATION OF MONOCYTES INTO FUNCTIONAL DENDRITIC CELLS AND IMMUNOTHERAPEUTIC COMPOSITIONS INCLUDING SUCH DENDRITIC CELLS	Examiner: Quang Nguyen
Serial Number: 09/294,494	
Filed On: April 20, 1999	(Docket No. 270425.0003)

PETITION UNDER 35 C.F.R. § 1.48
TO ADD JOINT INVENTOR

It is respectfully petitioned that the above-identified patent application be amended to add Carole L. Berger as a joint inventor. As set forth in detail in the Verified Statements of Dr. Richard L. Edelson and Dr. Carole L. Berger filed herewith and discussed more fully below, the patent application was made in the sole name of Richard L. Edelson through an error without any deceptive intention on the part of the actual inventors.

Dr. Richard L. Edelson was named as the sole inventor of the above-referenced patent application Serial No. 09/294,494 ("the '494 application") when it was filed on April 20, 1999.

In January 2002, the undersigned attorney worked with Dr. Edelson, Dr. Carole L. Berger and Dr. Douglas Hanson on preparation of a continuation-in-part of the '494 patent application. The continuation-in-part was filed January 31, 2002 and has been assigned Serial No. 10/066,021.

In the course of discussing inventorship of the inventions described in the continuation-in-part application, it became apparent that the inventorship on the parent application may have been erroneous. Accordingly, the undersigned attorney reviewed all available information regarding conception and development of the inventions claimed in the '494 application.

As set forth in the Verified Statements of Dr. Richard L. Edelson and Dr. Carole L. Berger filed herewith, Dr. Edelson and Dr. Berger have collaborated on research continuously since 1975, and they both worked at Yale University School of Medicine since 1991.

The research has been directed to the use of light activated drugs to externally treat human blood to reduce the functioning lymphocyte population in the blood in a process referred to as photopheresis.

In their work at Yale, Dr. Edelson has managed and directed the research programs, while Dr. Berger has been primarily responsible for managing and supervising the performance of research in the laboratory. Dr. Edelson and Dr. Berger work closely

together, discussing the results of research and testing, interpreting the meaning of test results, and discussing the direction of future testing.

In the course of their discussions, Dr. Edelson and Dr. Berger often exchange ideas and concepts for process improvements.

As shown in pages of her laboratory notebook attached to her Verified Statement as Exhibit 1, in July 1997, Dr. Berger noted the presence of an increased number of dendritic cells in the blood of a patient who had been treated periodically with photopheresis. As this was an unexpected result, Dr. Berger and Dr. Edelson discussed whether the photopheresis procedure might be responsible for directly or indirectly inducing conversion of blood monocytes into dendritic cells.

As shown in pages from her laboratory notebook dated December 8, 1997, further testing showed that the increased number of dendritic cells following the photopheresis procedure could persist in the patient's blood for at least a month.

Dr. Edelson and Dr. Berger discussed these results together at that time, and they jointly raised the possibility that the monocyte-to-dendritic cell conversion was induced by flow of a thin film of monocytes through the narrow plastic channels of a photopheresis device. At that time, it was unclear to Dr. Edelson and Dr. Berger how the dendritic cells could contribute to an immunotherapeutic response against tumor antigens.

After reading a scientific article in December 1998, which described the process by which dendritic cells present disease related antigens to induce an immune system response, Dr. Edelson conceived the idea that the dendritic cells observed following the photophersis process could be used to efficiently present cellular antigens derived from ingested apoptotic cells to CD8 cytotoxic T cells.

At the time that the '494 application was filed, Dr. Edelson was focused on the use of dendritic cells in immunotherapeutic treatments. As a result, Dr. Edelson, inadvertently and without deceptive intent, did not consider Dr. Berger's role in the conception of the portion of the claimed inventions involving conversion of monocytes into dendritic cells by flow of a thin film of monocytes through a narrow plastic channel.

After reviewing the pages from Dr. Berger's laboratory notebook and discussing the matter together and with the undersigned, both Dr. Edelson and Dr. Berger agree that Dr. Berger contributed to the conception of ideas regarding the induction of monocyte conversion to dendritic cells which are incorporated in the inventions claimed in the '494 application.

As soon as the error in inventorship became apparent, this Petition was diligently made. Accordingly, this Petition is timely.

In support of this Petition, Applicant submits the following:

(a) A Verified Statement of Facts by Dr. Richard L. Edelson;

(b) A Verified Statement of Facts by Dr. Carole L. Berger with Exhibits 1 and 2 attached;

(c) A Declaration, Power of Attorney and Petition Under 37 C.F.R. § 1.65, executed by both of the joint inventors, Richard L. Edelson and Carole L. Berger; and

(d) The fee required by 37 C.F.R. § 1.17 (h).

For the foregoing reasons, it is submitted that this amendment be entered and Carole L. Berger be added as a named co-inventor in the above-identified patent

application.

Date: July 29, 2002

Respectfully submitted,

Eric E. Grondahl
Reg. No. 46,741
Cummings & Lockwood LLP
Granite Square
700 State Street
P.O. Box 1960
New Haven, CT 06509-1960

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Serial No. 09/294,494
Art Unit: 1632

Attorney Docket No. 270425.0003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard Leslie Edelson	
	Group Art Unit: 1632
on METHODS FOR INDUCING THE DIFFERENTIATION OF MONOCYTES INTO FUNCTIONAL DENDRITIC CELLS AND IMMUNOTHERAPEUTIC COMPOSITIONS INCLUDING SUCH DENDRITIC CELLS	Examiner: Quang Nguyen
Serial Number: 09/294,494	
Filed On: April 20, 1999	(Docket No. 270425.0003)

VERIFIED STATEMENT OF FACTS BY
DR. RICHARD L. EDELSON, NAMED INVENTOR

I, Dr. Richard L. Edelson, residing at 76 Coleytown Road, Westport, Connecticut 06880, hereby declare as follows:

I am currently the Deputy Dean for Clinical Affairs and Chairman of the Department of Dermatology at the Yale University School of Medicine ("Yale"). I have been on the faculty of Yale since 1986.

I have been actively involved in research regarding therapeutic treatments using light activated drugs since 1975. I began this research while on the faculty at Columbia University, and I continued this research when I moved to Yale in 1986. During the 1980's and early 1990's, I was a named inventor on several patents claiming methods of using light activated drugs to externally treat human blood to reduce the functioning lymphocyte population in the blood.

Since 1975 when we performed research in the same laboratory at Columbia University, I have collaborated closely with Dr. Carole Berger. In 1986, I joined the faculty at Yale University, but continued to collaborate closely and co-author scientific papers with Dr. Berger. Our collaboration has been so close that in 1991, Dr. Berger moved to Yale University as well, so that we could discuss our common projects on a nearly daily basis. In the conduct of the research, I have been primarily responsible for managing the research programs, including responsibility for directing the course of the research. Dr. Berger is primarily responsible for managing and supervising the performance of the research. In the course of the research, Dr. Berger and I discuss the results of research and testing, interpret the results of the testing and the direction of future testing. In the course of these discussions, we often exchange ideas and concepts for process improvements.

Initially, the research programs on which Dr. Berger and I collaborated were directed primarily at improving the therapeutic treatment methods using light activated drugs that were described in several of the previously issued patents on which I was a named inventor. In the course of the research, it was discovered that certain

methods of treatment of blood resulted in conversion of a large number of monocytes into functional antigen presenting dendritic cells.

On April 20, 1999, patent application Serial Number 09/294,494 ("the '494 application") was filed with the United States Patent & Trademark Office describing and claiming methods for conversion of monocytes into functional antigen presenting dendritic cells and compositions derived from these methods. At the time that the patent '494 application was filed, I believed that I was the sole inventor of the immunotherapeutic treatment methods described and claimed in the application.

On January 31, 2002, a continuation-in-part patent application, Serial No. 10/066,021 ("the '021 application"), was filed claiming priority to the '494 application. The '021 application describes and claims improved methods for immunotherapeutic treatments using dendritic cells produced by the methods described and claimed in the '494 application. The inventors on that continuation-in-part application are Dr. Carole Berger, Dr. Douglas Hanlon and me.

During preparation of the '021 application, Dr. Berger brought to my attention the pages from her laboratory notebook discussed below which, in conjunction with discussions with Dr. Berger, refreshed my recollection regarding events which led to the conception of the methods described and claimed in the '494 application.

In approximately July 1997, in the course of conducting research related to the use of light activated drugs, certain phenomena became apparent which had not been previously known. Results of testing supervised by Dr. Berger, as reflected in pages from her laboratory notebook dated July 16, 1997 attached to her Verified Statement as Exhibit 1, indicated that treatment of blood in a photopheresis apparatus had

unexpectedly resulted in conversion of a large number of blood monocytes into dendritic cells. Dr. Berger discussed these unexpected results with me and together we conceived and developed programs for additional research.

As indicated by the page from Dr. Berger's laboratory notebook dated December 8, 1997 and attached to her Verified Statement as Exhibit 2, we determined that the dendritic cells derived as a result of the photopheresis procedure can persist for several weeks in a treated patient and can, therefore, initiate immunotherapeutic reactions in photopheresed patients. Because of the significance of this observation, at that time Dr. Berger and I discussed those results in detail and jointly raised the possibility that the monocyte-to-dendritic cell conversion was induced by flow of a thin film of monocytes through narrow plastic channels of a photopheresis device.

In December 1998, I read a scientific article which described the process by which dendritic cells present (via their class I major histocompatibility complexes) disease related antigens to induce an immune system response to disease effector agents. The data in this article led to my idea that dendritic cells activated by the photopheresis process, unlike the monocytes from which they develop, are able to efficiently present cellular antigens derived from ingested apoptotic cells to CD8 cytotoxic T cells. Shortly after reading this article, I conceived the methods and compositions described and claimed in the '494 application, i.e. an efficient method for loading dendritic cells with those relevant antigens necessary to produce desired immunotherapeutic effects. At the time that I was working on preparation of the '494 application, I was primarily focused on the use of the dendritic cells in immunotherapeutic treatments, and it did not occur to me at that time that Dr. Berger might be an inventor of the claimed methods as a result of

her involvement in the conception of the method of producing the dendritic cells by flow of a thin film of monocytes through a narrow plastic channel.

From my recent review of Dr. Berger's laboratory notebook pages and my recent discussions with Dr. Berger, I believe that Dr. Berger contributed directly to the conception of important ideas regarding the induction of monocyte conversion to dendritic cells. These ideas are incorporated in the inventions claimed in the '494 application. When I realized that there might be an error in the inventorship of the '494 application, I brought the matter to the attention of my attorney, who has diligently investigated the matter and filed the accompanying petition.

Based upon the facts described above, I believe that the inventions described and claimed in the above-identified patent application were developed in part by me, and in part by Dr. Carole Berger. The Oath and Declaration filed in connection with the '494 application erroneously states that I was the sole inventor of the inventions described in the application. I executed the erroneous Oath and Declaration without deceptive intent.

All statements made herein of my own knowledge are true. All statements made on information and belief are believed to be true. Furthermore, all statements herein are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated at New Haven, Connecticut this 24 day of July, 2002.

7/24/02
Date

Richard Edelson
Dr. Richard L. Edelson

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ATTORNEY DOCKET NO.:270425.0003

Declaration, Power of Attorney, and Petition

As a below named inventor, I/we hereby declare that:

My/Our residence, post office address and citizenship is/are as stated below next to my/our name(s),

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **METHODS FOR INDUCING THE DIFFERENTIATION OF MONOCYTES INTO FUNCTIONAL DENDRITIC CELLS AND IMMUNOTHERAPEUTIC COMPOSITIONS INCLUDING SUCH DENDRITIC CELLS,** the specification of which *(check one)*

☐ is attached hereto; or

☒ was filed on April 20, 1999 as Application Serial No. 09/294,494 and was amended on August 14, 2001 and May 7, 2002; or

PCT FILED APPLICATION ENTERING NATIONAL STAGE

☐ was described and claimed in International Application No. _____ filed on _____ and as amended on _____ (if applicable).

I/We hereby state that I/we have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above, and that it contains a full, clear, concise and exact description of the subject matter for which a patent is sought.

I/we acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

Prior Application(s)

☐ (Check if applicable) I/We hereby claim foreign priority benefits under Title 35, United States Code § 119, by checking the box(es) below, any foreign application(s) for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed and hereby incorporate the entire contents of which herein by reference:

Prior Foreign Application(s)
Priority Claimed?

(Number)	(Country)	Day/month/year filed	☐ Yes	☐ No
(Number)	(Country)	Day/month/year filed	☐ Yes	☐ No

☐ (Check if applicable) I/We hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Prior Provisional Application(s)

(Application Number)	(Filing Date)
(Application Number)	(Filing Date)

(*Note:* When the nonprovisional application is entitled to an earlier U.S. effective filing date of one or more provisional applications under Title 35, United States Code § 119(e), a statement such as "This application claims the benefit of U.S. Provisional Application No. _____, filed _____, and U.S. Provisional Application No. _____, filed _____ _____." should appear as the first sentence of the description. In view of this requirement, the right to rely on a prior application may be waived or refused by an applicant by refraining from inserting a reference to the prior application in the specification of the later one.)

☐ (Check if applicable) I/We hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I/we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. Application(s)

(Application Serial No.)	(Filing Date)	Status (Patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	Status (Patented, pending, abandoned)

☐ (Check if applicable) I/We hereby authorize the U.S. attorneys or agents named herein to accept and follow instructions from _____ as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the U.S. attorneys or agents named herein and myself/ourselves. In the event of a change, I/we will notify in writing the U.S. attorney or agent named herein.

☐ (Check if applicable) In this continuation-in-part application, insofar as the subject matter of any of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

I/We hereby declare that all statements made herein of my/our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I/we hereby appoint:

George Chaclas, Reg. No. 46,608
Daniel F. Coughlin, Reg. No. 36,111
Mark D. Giarratana, Reg. No. 32,615
Eric E. Grondahl, Reg. No. 46,741
Barry Kramer, Reg. No. 20,622
Basam E. Nabulsi, Reg. No. 31,645
Richard H. Newman, Reg. No. 41,222
R. Thomas Payne, Reg. No. 30,674
David J. Silvia, Reg. No. P-49,036
Scott D. Wofsy, Reg. No. 35,413

of the firm of CUMMINGS & LOCKWOOD,
whose address is Granite Square, 700 State Street,
P.O. Box 1960, New Haven, CT 06509-1960;

as my/our attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please address all written correspondence to the following address:

Eric E. Grondahl
CUMMINGS & LOCKWOOD
Granite Square
700 State Street
P.O. Box 1960
New Haven, CT 06509-1960

Telephone Calls should be directed to Eric E. Grondahl, by dialing (860) 275-6704.

Wherefore I/we pray that Letters Patent be granted to me/us for the invention or discovery described and claimed in the foregoing specification and claims, and I/we hereby subscribe my name to the foregoing specification and claims, declaration, power of attorney, and this petition.

Full name of first inventor: Richard Leslie Edelson

Residence: 76 Coleytown Road, Westport, CT 06880

Citizenship: USA
Post Office Address: 76 Coleytown Road, Westport, CT 06880

First Inventor's signature Richard Edelson

Date 7/24/02

Full name of second inventor: Carole Berger

Residence: 3935 Blackstone Avenue, Riverdale, Bronx, New York 10471

Citizenship: USA
Post Office Address: 3935 Blackstone Avenue, Riverdale, Bronx, New York 10471

Second Inventor's signature Carole L. Berger

Date 7/24/02

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Serial No. 09/294,494
Art Unit: 1632

Attorney Docket No. 270425.0003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard Leslie Edelson	
	Group Art Unit: 1632
on METHODS FOR INDUCING THE DIFFERENTIATION OF MONOCYTES INTO FUNCTIONAL DENDRITIC CELLS AND IMMUNOTHERAPEUTIC COMPOSITIONS INCLUDING SUCH DENDRITIC CELLS	Examiner: Quang Nguyen
Serial Number: 09/294,494	
Filed On: April 20, 1999	(Docket No. 270425.0003)

VERIFIED STATEMENT OF FACTS BY
DR. CAROLE L. BERGER, UNNAMED INVENTOR

I, Dr. Carole L. Berger, residing at 3935 Blackstone Avenue, Riverdale, Bronx, New York 10471, hereby declare as follows:

I am currently a Research Scientist on the faculty of the Department of Dermatology at the Yale University School of Medicine ("Yale"). I have been on the faculty at Yale since 1991.

Dr. Richard Edelson and I have collaborated continuously since 1975, when we worked in the same laboratory at Columbia University. This research collaboration continued from a distance when Dr. Edelson moved to Yale University in 1986. In 1991, I joined the department which Dr. Edelson chairs at Yale and since that time Dr. Edelson and I have discussed our collaborative research on an almost daily basis. This collaborative research, from the beginning of the relationship in the 1970s, has involved therapeutic treatments using light activated drugs to externally treat human blood to reduce the functioning lymphocyte population in the blood.

In my Yale University work with him, Dr. Edelson has managed and directed the research programs. I have been primarily responsible for managing and supervising the performance of research in the laboratory.

From the beginning of our work together, Dr. Edelson and I have discussed the results of research and testing, interpretation of the meaning of test results, and the direction of future testing. In the course of these discussions, Dr. Edelson and I often exchange ideas and concepts for process improvements and we discuss together the course of future research programs.

As shown in the pages from my laboratory notebook attached to this Statement as Exhibit 1, in July 1997, I noted the presence of an increased number of dendritic cells in blood of a patient who had been treated periodically with photopheresis. As this was an unexpected result, I discussed my findings with Dr. Edelson. Dr. Edelson and I discussed the possibility that the photopheresis procedure might be responsible for directly or indirectly inducing conversion of monocytes to dendritic cells. We wondered whether this was a phenomenon limited to this single patient, whether such dendritic cell

induction might be a general feature of photopheresis and whether the dendritic cells induced by photopheresis might be responsible for the potent immunotherapeutic effects of the treatment.

As shown in the page from my laboratory notebook dated December 8, 1997, we found that the increased number of dendritic cells as a result of the photopheresis procedure could persist in the patient's blood for at least a month. This was an intriguing result, which I discussed with Dr. Edelson, since this finding suggested that the induced dendritic cells might be responsible for the immunotherapeutic benefits accruing from photopheresis. Dr. Edelson and I reasoned that photopheresed monocytes might convert to dendritic cells after return of the treated blood to the patient. Together, we hypothesized that, after becoming activated by their transient adherence to the plastic chamber in the photopheresis device, monocytes might begin to differentiate into immature dendritic cells. Although we considered it likely that these new dendritic cells contribute to the anti-cancer immune responses that photopheresis can stimulate, it was not clear to us at that time how the new dendritic cells might access and process the antigens distinctive of the malignant cells and then stimulate a clinically relevant immune response against these tumor antigens.

In January, 2002, I worked with Dr. Edelson on a patent application which was a continuation-in-part of a patent application, Serial No. 09/294,494 ("the '494 application") previously filed by Dr. Edelson. The Continuation-in-Part application has been assigned Serial No. 10/066,021 ("the '021 application"). The '021 application describes and claims improved methods for immunotherapeutic uses of the dendritic cells

produced by the methods initially conceived by Dr. Edelson and me. The improved methods were conceived by Dr. Edelson, Dr. Douglas Hanson and me together.

During preparation of the '021 application, Dr. Edelson and I discussed my activities in connection with the invention of the methods and compositions claimed in the previously filed '494 application. I reminded Dr. Edelson that, although the '494 patent was filed to protect the proprietary rights stemming from his December 1998 conception of how dendritic cells, produced via transient adherence of monocytes to a plastic surface, are able to acquire and present tumor antigens, we had in 1997 jointly conceived the included prerequisite step of how those dendritic cells are produced. Therefore, the '494 application contained critical elements jointly conceived by Dr. Edelson and me.

As a result of these discussions, Dr. Edelson and I requested that the attorney currently prosecuting the '494 application, Eric Grondahl, investigate whether I should be named as an inventor on the '494 patent application. I discussed with Attorney Grondahl my activities in connection with the inventions described in the '494 application as described above, and provided him copies of the pages from my Laboratory Notebook. Upon determining that an error in inventorship had inadvertantly occurred without deceptive intent regarding the '494 application, the accompanying Petition was diligently filed.

All statements made herein of my own knowledge are true. All statements made on information and belief are believed to be true. Furthermore, all statements herein are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated at New Haven, Connecticut this 24 day of July, 2002

7/24/02
Date

Carole L. Berger
Dr. Carole L. Berger

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